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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/089,846	06/06/2002	John Carter	3920-0110P	5250

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EXAMINER	
CHOI, FRANK I	
ART UNIT	**PAPER NUMBER**
1616	

DATE MAILED: 12/22/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/089,846	CARTER, JOHN	
	Examiner	Art Unit	
	Frank I. Choi	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 July 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *57-158* is/are pending in the application.

4a) Of the above claim(s) *63,86,102,118,144 and 156* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *70-79,89-96,98,99,101,103-108,121-134,146-148,151-155 and 157* is/are rejected.

7)☒ Claim(s) *57-62,64-69,80-85,87,88,97,100,109-117,119,120,135-143,145,149,150 and 158* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date ____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Objections

Claims 97,100,149,150,158 are objected to as being dependent upon a rejected base claim, but would be allowable to the extent the claim reads on the elected invention if rewritten in independent form including all of the limitations of the base claim and any intervening claims. Examiner did not state that the claims would be allowable if one merely recited sublimed sulfur; the claims must be directed to the elected invention: the elected species are copper orotate, manganese orotate, iron orotate, zinc orotate, sodium salicylate, assimilable sulfur and proline.

Claims 57-62,64-69 are allowable to the extent the claims read on the elected invention as limited by the limitation "elemental sulfur" and claims 80-85,87, 88, 109-117,119,120, 135-143,145 are allowable to the extent the claims read on the elected invention, however, the claims are objected to as they are broader in scope than the elected invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 70-79, 89-96,98,99,101,103-108,121-134, 146-148,151-155, 157 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jackson et al. (US Pat. 5,654,011) in view of Riley et al. (US Pat. 5,948,443, Wawretschek et al. (US Pat. 4,061,741), Herschler (US Pat. 4,514,421), Herschler (US Pat. 4,616,039) and Bounous et al. (US Pat. 5,290,571).

Jackson et al. disclose compositions and methods for providing dietary supplements to med the needs of pre-perimenopausal women, including pregnant women, and to reduce the risk of cancer comprising copper, manganese, zinc, iron and vitamin C (Column 2, lines 25-51, Column 4, lines 13-23, Column 8, lines 30-68).

Riley et al. discloses a composition and method of reducing the risk of cancer by providing dietary supplements to women which comprise aspirin or bioequivalent forms, such as salicylic acid or other salicylates, iron, zinc, manganese, copper and Vitamin C (Column 9, lines 30-55, Column 21, lines 7-63,Table III).

Wawretschek et al. disclose that the analgesic efficiency of sodium salicylate can be reinforced by combining with a salt of orotic acid (Claims 10, 30,39).

Hershler (US Pat. 4,514,421) disclose that administration of methylsulfonylmethane (MSM) and ascorbic acid and that administration of MSM resulted in reduction of tumor mass (Column 12, lines 7-47).

Hershler (US Pat. 4,616,039) disclose that methylsulfonylmethane is an assimilable source of sulfur (Abstract).

Bounous et al. disclose a composition containing proline to which is added vitamin C, iron, zinc, copper which is used to treat cancer (Column 6, lines 10-31,Table 1, Column 7, Column 24, lines 25-68, Table 10).

The difference between the prior art and the claimed invention is that the prior art does not expressly disclose the use of copper orotate, manganese orotate, iron orotate, sodium salicylate, a source of assimilable sulfur, proline and vitamin C. However, the prior art amply suggests the same as the prior art discloses dietary supplements which combine various nutrients,

such as copper, manganese, vitamin C with salicylates for use in women and reducing the risk of cancer, the combination of sodium salicylate and salts of orotate to increase the efficacy of the sodium salicylate, the use of copper, manganese, iron and vitamin C for use in pregnant women and reducing the risk of cancer, MSM for treatment of cancer and proline which can be combined with other nutrients, such as copper, iron, zinc and vitamin C and is used to treat cancer. As such, it would have been well within the skill of and one of ordinary skill in the art would have been motivated to modify the prior art by providing the copper, iron, zinc and manganese as salts of orotate so as to increase the efficacy of the sodium salicylate and to combine copper, iron, zinc and manganese with sodium salicylate and vitamin C with the expectation that the composition would be suitable for use in pregnant women and for treatment of cancer, to further add proline with the expectation that the same would be suitable for treatment cancer and to add MSM as it is effective in treating cancer.

Examiner has duly considered Applicant's arguments but deems them unpersuasive.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 231 USPQ 375 (Fed. Cir. 1986). Further, the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 208 USPQ 871 (CCPA 1981).

The arguments of counsel cannot take the place of evidence in the record. In re Schulze,145 USPQ 716, 718 (CCPA 1965); In re Geisler, 43 USPQ2d 1362 (Fed. Cir. 1997) ("An assertion of what seems to follow from common experience is just attorney argument and not the kind of factual evidence that is required to rebut a prima facie case of obviousness.").

The reason or motivation to modify the reference may often suggest what the inventor has done, but for a different purpose or to solve a different problem. It is not necessary that the prior art suggest the combination to achieve the same advantage or result discovered by applicant. In re Linter, 173 USPQ 560 (CCPA 1972); In re Dillon,16 USPQ2d 1897 (Fed. Cir. 1990), cert. denied, 500 U.S. 904 (1991).

There is no requirement that Jackson disclose the use of salicylic acid, or assimilable sulfur or the treatment of cancer. Further, Applicant provides no evidence that the biochemical mechanisms involved in reducing the risk of cancer and different from those mechanisms for treating cancer. The claims do not exclude calcium and Applicant provides not evidence supporting the arguments relative to calcium. See, for example, US Pat. 6,451,341, column 15, lines 13, 15(calcium may protect against certain types of cancer, such as colon cancer).

There is no requirement that Riley disclose the use of assimilable sulfur or the treatment of cancer. The fact that Riley discloses reducing the risk of CHD does not overcome the fact that Riley discloses the use of aspirin to reduce the risk of certain cancers.

There is no requirement that Wawreschek disclose the use of metal salts of orotic acid. Salts of metals are clearly suggested by the combined teachings of the prior art and it is well within the skill of one ordinary skill in the art to prepare metal salts of orotic acid with the expectation that the same would be effective in treating cancer.

There is no requirement that Herschler '421 disclose the use of copper or that any other sourse of assimilable sulfur be disclosed. Applicant cites to disclosure in Herschler '421 which does disclose the combination of MSM with aspirin and vitamin C. Herschler '421 specifically discloses that MSM reduced tumor mass.

There is no requirement that Hershler '039 disclose the use of copper, any other source of asimilable sulfur or the combination of MSM with aspirin or vitamin C or the treatment of cancer.

There is no requirement that proline be present as a free amino acid or the use of salicylic acid or sulfur. Contrary to Applicant's arguments Bounous et al. specifically discloses the treatment of cancer (Bounous et al. Column 24, lines 25-68, Table 10).

With respect to claims 70, 124 disclosed examples and preferred embodiments do not constitute a teaching away from a broader disclosure or nonpreferred embodiments. In re Susi, 169 USPQ 423 (CCPA 1971). Applicant reference to specific embodiments does not exclude amounts falling above and below the specific embodiments. It would be well within the skill of and one of ordinary skill in the art to vary amounts depending on efficacy in the reduction of risk of cancer or treatment of cancer. Applicant refers to a preferred embodiment including gluconate salts, however, gluconate salts are not part of the elected invention.

With respect to claims 89,121, 124, 146 one of ordinary skill in the art would be motivated to use copper, salicylic acid and vitamin C to reduce the risk of further cancers in patients undergoing treatment for cancer as well as provide nutrients and the benefits of salicylic acid.

With respect to claim 146, claim 146 does use the product of claim 80 as claim 146 does indicate that the components are the sole pharmacologically active components.

Therefore, the claimed invention, as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, because every element of the invention has been collectively taught by the combined teachings of the references.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

A facsimile center has been established in Technology Center 1600. The hours of operation are Monday through Friday, 8:45 AM to 4:45 PM. The telecopier number for accessing the facsimile machine is 571-273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Choi whose telephone number is (571)272-0610. Examiner maintains a flexible schedule. However, Examiner may generally be reached Monday-Friday, 8:00 am – 5:30 pm (EST), except the first Friday of the each biweek which is Examiner's normally scheduled day off.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Mr. Gary Kunz, can be reached at 571-272-0887. Additionally, Technology Center 1600's Receptionist and Customer Service can be reached at (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

FIC
December 17, 2005

JOHN PAK
PRIMARY EXAMINER
GROUP 1600